REMARKS

Status of the Claims

Claims 1-6 and 9-18 are pending, with claim 1, 16 and 17 being independent. Without conceding the propriety of the rejections, claim 10 has been amended to correct an inadvertent typographical error. Support for the claim amendment can be found throughout the specification, including the claims. Therefore, no new matter has been added.

Initially, Applicants are pleased to note that claims 17 and 18 are indicated as allowed.

As requested, Applicants will provide a list of co-pending and related applications for the present inventive entity in the form of an Information Disclosure Statement submitted under separate cover.

Applicant respectfully requests the Examiner to reconsider and withdraw the outstanding rejections in view of the foregoing amendments and the following remarks.

Rejection under 35 U.S.C. § 103(a)

Claims 1-6 and 9-16 are rejected under 35 U.S.C. § 103(a) as allegedly being obvious over U.S. Patent Application Publication No. 2005/0249811 (Plachetka). Applicants respectfully disagree with the rejection; therefore, this rejection is respectfully traversed.

M.P.E.P. § 2142 provides that "to establish a prima facie case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations." Furthermore, if an independent claim is nonobvious under 35 U.S.C. § 103, then any claim depending therefrom is nonobvious. *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988).

Plachetka relates to pharmaceutical compositions for the coordinated delivery of NSAIDS. The compositions of Plachetka are designed to have a reduced likelihood of causing unwanted side effects, especially gastrointestinal side effects. (paragraph [0002]). Plachetka discloses a single, coordinated, unit-dose product that combines (a) an agent that actively raises intragastric pH to levels associated with less risk of NSAID-induced ulcers (an

"acid inhibitor") and (b) an NSAID. (paragraph [0011]). Plachetka discloses that the acid inhibitor can be a H2 blocker ***or*** a proton pump inhibitor.

In Example 1, Plachetka discloses an enteric coated NSAID (Naproxen) core wherein the Naproxen core is coated with a cellulose layer, an enteric coating preventing the release of Naproxen in the stomach, and an outermost layer containing the "acid inhibitor". In this example the "acid inhibitor" is a H2 blocker, specifically famotidine.

In Examples 5 and 6, Plachetka discloses an enteric coated Naproxen core and an outermost layer containing a proton pump inhibitor as the "acid inhibitor", specifically pantoprazole (example 5) and omeprazole (example 6).

Accordingly, Plachetka discloses a multilayer formulation comprising a NSAID core with an enteric coating and an outermost layer containing either a H2 blocker ***or*** a proton pump inhibitor.

In contrast, the presently claimed invention relates to a pharmaceutical composition for the treatment of diseases related to gastric hyperacidity, wherein it contains a combination of one or more histamine H2-receptor antagonists ***and*** specifically tenatoprazole. Applicants respectfully submit that Plachetka does not disclose or suggest the presently claimed pharmaceutical composition comprising ***a combination of one or more histamine H2-receptor antagonists and specifically tenatoprazole*** as the actives.

As disclosed in the present specification, the studies performed by the Applicant have shown that the combination of a *specifically* tenatoprazole and a histamine H2-receptor antagonist procures *unexpected effects* which compared with other proton pump inhibitors and other histamine H2-receptor antagonists, used alone or in combination. (page 3, lines 7-12). Applicant further discloses that it has been shown that the combination of tenatoprazole and one or more histamine H2-receptor antagonists enables control of gastric acidity which is *markedly superior* to that achieved with each of the components used alone, and particularly allows the effective treatment of patients suffering from symptoms and lesions related to gastroesophageal reflux and refractory to standard therapy. (page 3, lines 12-19 and page 6, line 32 – page 7, line 12).

In light of at least the foregoing, Applicants respectfully request that the rejection of claims 1-6 and 9-16 as allegedly obvious over Plachetka be withdrawn.

Conclusion

For the reasons noted above, the art of record does not disclose or suggest the present claims.

In view of the foregoing amendments and remarks, reconsideration of the claims and allowance of the subject application is earnestly solicited. The Examiner is invited to contact the undersigned at the below-listed telephone number, if it is believed that prosecution of this application may be assisted thereby.

Respectfully submitted,

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